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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,375	03/14/2001	Shaorong Liu	PB0006	3335

22840 7590 05/06/2003  
AMERSHAM BIOSCIENCES  
PATENT DEPARTMENT  
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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT PAPER NUMBER

1753

DATE MAILED: 05/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/808,375

Applicant(s)

LIU, SHAORONG

Examiner

ALEX NOGUEROLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 March 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

***Drawings***

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "22" has been used to designate both a channel segment and a well in Figure 2. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to because many of the lines are too faint. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

3. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a) Claim 4 recites the limitation "loading segment" in line 3. There is insufficient antecedent basis for this limitation in the claim.

*Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Manz (US 5,296,114). Manz teaches a shaped microfabricated capillary array electrophoresis chip (the abstract; Figure 1; and col. 4, ll. 14-16) comprising

a planar substrate (element 1 in Figure 1) having a first major surface defining converging first and second elongate separate channels (any pair of intersecting channel sections, such as, 5 and 6 or 8 and 7), wherein each separation channel section extends between an associated cathode port and an anode port defined by the first major surface (at the end of each channel section is one of the electrode ports 20-27), wherein the substrate further comprises a first perimetrical edge segment extending substantially along the first separation channel section; and a second perimetrical edge segment extending substantially along the second separation channel section (as seen in Figure 1 each channel section is close to and parallel to an edge of the chip).

Note that Manz teaches that the chip does not have to be rectangular; he teaches a general n-sided figure, which preferably has at least three sides (col. 6, ll. 38-46).

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For claim 10 note that since Manz teach a shaped capillary electrophoresis chip having a first major surface, converging first and second elongate separation channels, and first and second perimetrical edge segments as claimed, they must have been provided or formed.

*Claim Rejections - 35 USC § 103*

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zanzucchi et al. (US 5,755,942) in view of Roach et al. (WO 00/02038 A1).

Addressing claims 1 and 10, Zanzucchi et al. teaches a shaped microfabricated capillary array electrophoresis chip (the abstract; Figures 1B and 2; col. 2, ll. 23-32; and col. 4, ll. 55-62) comprising

a planar substrate (element 48 in Figure 1B and Figure 2) having a first major surface

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defining a first channel that extends between an associated cathode port and an anode port defined by the first major surface (implied by col. 7, ll. 20-45, which teaches forming electrodes in some of the wells to create electrokinetic pumps), wherein the substrate further comprises a first perimetrical edge segment extending substantially along the channel; and a second perimetrical edge segment extending substantially along the second channel (Figure 2).

Zanzucchi et al. does not mention having a second channel on the first surface that converges with the first channel, although it should be noted that Zanzucchi et al. does teach having more than one channel on the first surface (Figure 7B and col. 6, ll. 31-50). Zanzucchi et al. also does not mention that the channels are separation channels, although this is arguably just intended use and does not further structurally and thus patentably distinguish the claimed invention. Roach et al. teaches an electrophoresis chip comprising a plurality of converging elongate separation channels, wherein each separation channel extends between an associated cathode port and an anode port defined by a first major surface (the abstract and Figure 8). It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a plurality of converging elongate separation channels as taught by Roach et al. in a module of Zanzucchi et al. because this will increase the complexity of linked processes or independent operations that can be performed with the microlaboratory disc. For example, by providing a plurality of converging elongate separation channels as taught by Roach et al. a sample can be electrophoretically separated and analyzed before or after processing in the other modules located on the microlaboratory disc supporting the modules, or electrophoresis of one group of samples can be performed while other groups of samples undergo independent processes in the other modules. The radial configuration of elongate separation channels taught

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by Roach et al. is advantageous because “no bends or turns are present between the injection region and the detection region. The bends or turns degrade the separations and may preclude the high resolution separations required for DNA sequencing” (page 16, line 36 – page 17, line 2).

For claim 10 note that since Zanzucchi et al. as modified by Roach et al. teach a shaped capillary electrophoresis chip having a first major surface, converging first and second elongate separation channels, and first and second perimetrical edge segments as claimed they must have been provided or formed.

Addressing claim 2, element 126 in Figure 8 of Roach et al. is a common anode port (page 16, lines 24-26).

Addressing claim 3, as seen in Figure 8 of Roach et al. for each paired sample port 135 and waste port 133 there is fluid communication across a loading segment of a single separation channel.

Addressing claim 4, as seen in Figure 8 of Roach et al. the separation channels extend linearly as claimed.

Addressing claims 5, 6, 11, and 12, as seen in Figure 2 of Zanzucchi et al. the first perimetrical edge and second perimetrical edge are oriented at an angle therebetween being a fraction of 180 degrees. Barring evidence to the contrary such as unexpected results, whether the angle is a whole fraction of 180 degrees is just a matter of convenience, so for example, that the modules may be readily interchanged.

Addressing claim 7, it should be first noted that whether an electrode port is an anode port or a cathode port is intended use. Anode port 126 in Figure 8 of Roach et al., which is in fluid communication with a pair of elongate separation channels, could readily be used as a cathode port just by switching the polarity of the applied voltage. In any event, if a pair of elongate separation channels are to have the same voltage applied across them it would have been obvious to one with ordinary skill in the art at the time the invention was made to have a cathode port in fluid communication with a pair of elongate separation channels because this will be more efficient by avoiding duplication of parts, such as ports, electrodes and electrical connections.

Addressing claims 8 and 17, although not mentioned in Zanzucchi et al. as modified by Roach et al. it would have been obvious to one with ordinary skill in the art at the time the invention was made to group together the separation channels to form a plurality of separation channel groups because this will be more efficient by avoiding duplication of parts, such as ports, electrodes and electrical connections. For example, if all the separation channels within a particular separation channel group are to have the same voltage applied across them providing



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multiple cathode and anode ports with associated electrodes and electrical circuitry would be wasteful.

Addressing claims 9 and 18, element 126 in Figure 8 of Roach et al. is a common anode port (page 16, lines 24-26). Again, it would have been obvious to one with ordinary skill in the art at the time the invention was to provide shared elements between or among the elongate separation channels to avoid wasteful duplication of parts.

Addressing claim 13, as seen in Figure 8 of Roach et al. the first channel (say the leftmost channel 123) extends in fluid communication between a first cathode port (131) and an anode port (126), so the first cathode port and the anode port must have been formed.

Addressing claim 14, a second cathode as claimed may be seen in Figure 8 (the rightmost cathode port 131), so the second cathode port must have been formed.

Addressing claim 15, element 133 is a waste port and element 135 is a sample port. Since they exist, they were formed.

Addressing claim 16, a sample channel (unlabeled) connate to the sample port is shown linearly extending between the loading segment and the anode port.

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Addressing claim 20, it would have been obvious to one with ordinary skill in the art at the time the invention was to engage a first chip and a second chip as claimed because as taught by Zanzucchi et al. "tests can [then] be performed on a large number of modules **48** in parallel" (col. 4, ll. 59-62).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (703) 305-5686. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (703) 308-3322. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

  
Alex Nogueroles  
May 2, 2003